REMARKS

Claims 1-37, 87-90, and 161-171 are pending in the patent application.

The Applicants are submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca ("the DelDuca Fourth Declaration") (Exhibit 1) to assist in explaining the phrase "turns brown in a natural time period" as recited in claims 1, 22 and 161. The Applicants note that Mr. DelDuca previously submitted three declarations to assist in explaining the invention, showing the non-obviousness of the invention and explaining the applied prior art.[1]

Reconsideration of the pending claims is respectfully requested.

I. 35 U.S.C. § 112, Second Paragraph, Rejection

The Office Action states that the phrase "turns brown in a natural time period" as recited in independent claims 1, 22 and 161 is indefinite. The Applicants respectfully disagree and to assist in supporting that the phrase "turns brown in a natural time period" is not indefinite, the Applicants are submitting the DelDuca Fourth Declaration.

The phrase "turns brown in a natural time period" is a phrase that is used and understood by those skilled in the art. DelDuca Fourth Decl. ¶ 4. This phrase has been used in correspondence related to meat-packaging systems between retailers and myself. *Id.* Specifically, this phrase has been used by those skilled in the art in the context of the color of the meat pigment. *Id.*

The portion "turns brown" of the phrase "turns brown in a natural time period" means that the piece of meat has some brown, but does not mean that the piece of meat has to be 100% brown. DelDuca Fourth Decl. ¶ 6. Retailers and food packers use the phrase "turns brown" in the context of whether most customers would consider the color of the meat pigment undesirable such that the customers would not purchase the meat. *Id.* The phrase "turns brown" is frequently used by retailers and food packers and, thus, is not indefinite. *Id.* The term "natural time period" of the phrase "turns brown in a natural time period" cannot be uniquely defined because the color of the meat pigment varies between the type of meat and the conditions

[1] DelDuca Declaration filed on September 8, 2003; DelDuca Second Declaration filed on June 16, 2004; and DelDuca Third Declaration filed on May 10, 2005.

for displaying such meat. DelDuca Fourth Decl. ¶ 7; *see* page 20, lines 17-26 of the present application ("The display times varied based on product type, initial microbial loads and storage conditions."). The natural time period for the meat pigment turning brown is not the same between ground beef, strip loins (strip steaks), inside portion of inside round steaks, outer portion of inside rounds steaks, and tenderloins. DelDuca Fourth Decl. ¶ 7. For example, the natural time period in which the meat pigment turns brown is about 4 days for strip steaks, while the natural time period in which the meat pigment turns brown for tenderloin is about 1 day. *Id.*

One example of this phrase being used in the published literature is Principles and Applications of Modified Atmosphere Packaging of Food (1993), which is Exhibit A of the DelDuca Fourth Declaration. DelDuca Fourth Decl. ¶ 5; On page 283, the literature discusses the effect of the meat turning brown in connection with conventionally overwrapped trays and also discusses that the color stability is limited on the shelf-life depending on type of meat (muscle). *Id.*

In summary, the phrase "turns brown in a natural time period" as used in the context of independent claims 1, 22 and 161 is understood by those skilled in the art and, therefore, is not an indefinite phrase in this context. Thus, the § 112 rejection, second paragraph, rejection should be withdrawn.

II. 35 U.S.C. § 103(a) Rejections

As acknowledged by the Examiner, U.S. Patent No. 6,054,153 to Carr ("Carr") and U.S. Patent No. 5,711,978 to Breen ("Breen") do not disclose, teach or suggest the use of carbon monoxide (CO). *See* pages 3, 6 and 7 of the Office Action. The Office Action applies a number of references -- U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); DE 1935566 A to Verbruggen ("Verbruggen"); and U.S. Patent No. 6,042,859 to Shaklai ("Shaklai") in an attempt to cure this deficiency in Carr and Breen. It would not have been obvious to combine Carr or Breen in view of other references such as Koch, Woodruff, Verbruggen and/or Shaklai to arrive at the present invention.

III. Applicants Previously Presented Evidence Of Non-Obviousness Of Independent Claims 1, 22 And 161

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants previously submitted evidence of non-obviousness in the form of two declarations in the Amendment and Response to Office Action that was filed on June 16, 2004 -- the Hunt Declaration (Exhibit 1 of the Prior Response) and the DelDuca Second Declaration (Exhibit 2 of the Prior Response). Some of the evidence presented was directed to the understanding that those of ordinary skill in the art, prior to the Applicants' invention, believed that CO "fixed" the color of the meat pigment.

A. Prior To The Applicants' Invention, Those Of Ordinary Skill In The Art Believed That CO Fixed The Color Of The Meat Pigment

Specifically, the Applicants submitted evidence that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment:

(a) CO not allowed with fresh meat in the U.S. since at least 1962, until Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concern of "fixing" the meat color;

(b) In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.";

(c) A previously applied reference in this application "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" from *Meat Science* to Sorheim et al. ("Sorheim")) disclosed that its meat packaging systems with a modified atmosphere of "0.4% CO/60% CO_2/40% N_2 had a bright stable red colour that lasted beyond the time of spoilage." Abstract of Sorheim; and

(d) Dr. Hunt, who has extensive experience in the processing of meats using modified atmosphere packaging, stated that it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.

B. The Applied References Of Shaklai And Koch Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

In response to the overwhelming submitted evidence that those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment, the Office Action states that (a) "Shaklai is relied on as evidence that the color of meat pigment exposed to CO is not fixed [on] the meat surface and that the meat surface will brown upon exposure to air depending on the time the meat is exposed to the CO"; and (b) "Koch et al. provide evidence that CO is removably associated with a meat surface so that the meat browns in a natural time period." Page 5 of the Office Action.

Neither Shaklai nor Koch teaches or suggests the claimed limitation in independent claims "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second package," that is specifically recited in independent claims 1, 22 and 161. Furthermore, there is no motivation to combine Shaklai and/or Koch with the other applied references in the pending rejections.

1. Shaklai Teaches That CO "Fixes" The Color Of The Meat Pigment (I.e., Extends Color Life)

Since Shaklai teaches that CO "fixes" the color of the meat pigment after exposure to the atmosphere, there would be no motivation to one of ordinary skill in the art to combine Shaklai with (a) Carr, Koch and Woodruff; or (b) Breen, Koch, Woodruff and Verbruggen as in the pending rejections.

Specifically, Shaklai discloses exposing raw meat to an atmosphere consisting essentially of CO in which the meat is "completely immersed or saturated" with CO. *See* col. 5, lines 29-37. "More specifically, a cross-section of meat is completely immersed in or saturated to its core with carbon monoxide from the exposed surfaces through the entire cross-section (thickness) including its core region and retains the carbon monoxide until the meat is cooked. Thus, as stated above, the meat is preserved throughout its thickness." Col. 5, lines 38-43 of Shaklai.

Shaklai continues by stating that "[p]ractically all of the carbon monoxide (over 99.9%) taken up by meat will be maintained as hemoglobin and myoglobin (Hb/Mb) bound forms." Col. 5, lines 57-59. Shaklai also discloses that "[b]oth hemoglobin and myoglobin bind carbon

mechanism for carbon monoxide preserving of meat is the much greater affinity of myoglobin for carbon monoxide than for oxygen." Col. 6, lines 26-28 of Shaklai.

As previously submitted, it is known to those of ordinary skill in the art that when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen does with hemoglobin. Therefore, one of ordinary skill in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. Previously sumitted DelDuca Third Decl. ¶ 4. In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Applicants' invention, would not have been expected to degrade in a natural time period. DelDuca Third Decl. ¶ 4.

The examples of Shaklai also support that the meat pigment is "fixed" beyond its natural time period. Specifically, Example 4 of Shaklai (mentioned at page 5 of the Office Action) discloses that (a) meat treated with CO on day 14 had only a surface (less than 1 mm deep) being brown, while (b) meat treated with air was dark brown throughout. Col. 9, lines 40-50. Thus, it is clear that the meat pigment in Example 4 was "fixed" because it extended the color of meat pigment past its natural time period after being exposed to the atmosphere. This is further illustrated in Example 3 of Shaklai where the air-treated meat and CO-treated meat had different colors – the air-treated meat after 3 days was all brown and the CO-treated meat was a wine-red color. Col. 9, lines 10-19. Example 2 of Shaklai mentioned at page 5 of the Office Action also does not support that meat pigment is not "fixed" beyond its natural time period (air-treated samples were brown and CO-treated samples were a bright wine red after 24 hours). Col. 8, line 50-col. 9, line 5.

The Office Action asserts that Shaklai is now relied on as not fixing the color of the meat pigment surface. Page 5 of the Office Action. This ignores the evidence in the above examples that Shaklai discloses that the color of the meat pigment is fixed. There is no expectation in Shaklai that by applying the levels disclosed in Woodruff that the meat would brown in a natural time period.

Thus, because Shaklai discloses "fixing" the color of the meat pigment, there would be no motivation to one of ordinary skill in the art to combine Shaklai with (a) Carr, Koch and Woodruff or (b) Breen, Koch, Woodruff; and Verbruggen as in the pending rejections because Shaklai discloses "fixing" the color of the meat pigment.

2. Koch Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of its CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with (a) Carr, Shaklai and Woodruff; or (b) Breen, Shaklai, Woodruff and Verbruggen as in the pending rejections.

Specifically, Koch discloses wrapping meat with a CO-containing film such that CO is transferred from the film to contact the surface of the meat. *See*, abstract. An object of Koch is to include a relatively small quantity of CO that is gradually released from the CO-containing film. Col. 2, lines 18-22. Koch discloses (a) covering primal cuts made at a slaughterhouse with a CO-containing film, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc. Col. 3, lines 4-8.

Since Koch discloses a large quantity of meat (primal cuts) exposed to a small quantity of CO, it would not be reasonable that the non-surface meat pigments of the primal cuts would have been exposed to CO. *See* DelDuca Third Decl. ¶ 7.

First, Koch does not disclose the exact weight of the primal cuts of meat. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. DelDuca Third Decl. ¶ 6. The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. DelDuca Third Decl. ¶ 6. Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat. DelDuca Third Decl. ¶ 6.

Second, the disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. *See* col. 9, lines 11-28 of Shaklai and DelDuca Third Decl. ¶ 7. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments to carboxymyoglobin. DelDuca Third Decl. ¶ 7.

Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film. DelDuca Third Decl. ¶ 7. It would be expected

that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also not been exposed to CO. DelDuca Third Decl. ¶ 8. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts not exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. DelDuca Third Decl. ¶ 8. Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film. DelDuca Third Decl. ¶ 8.

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with (a) Carr, Shaklai and Woodruff; or (b) Breen, Shaklai, Woodruff and Verbruggen as in the pending rejections.

In summary, neither Shaklai nor Koch teaches or suggests that the meat pigment upon exposure to CO does not "fix" the color of the meat pigment after exposure to the atmosphere.

IV. Independent Claims 1, 22 and 161

Therefore, the submitted evidence summarized above indicates that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment after exposure to the atmosphere.

The only apparent mention about the submitted evidence summarized above in this Office Action is that FDA regulatory laws are not relevant to the issue of obviousness in this case. *See* page 11 of the Office Action. The Office Action is silent on Sorheim, which clearly states that CO in the amount of 0.4% used in a meat-packaging system had a bright red color that lasted beyond the time of spoilage. The Office Action is also silent on the 1962 letter to Whirlpool about the lack of data showing that the color of the meat pigment is not being fixed. The Office Action is also silent about the statement of Dr. Hunt, who is one skilled in the art, that it was understood by those skilled in the art that CO fixes the color of the meat pigment. The applied references of Koch and Shaklai do not alter that conclusion.

It would, therefore, be expected prior to the Applicants' invention that the CO levels disclosed in U.S. Patent No. 4,522,835 to Woodruff ("Woodruff") would "fix" the color of the meat pigment after exposure to the atmosphere. Thus, there would be no motivation to combine

(a) Carr, Koch, Woodruff, Shaklai or any combination thereof; or (b) Breen, Koch, Woodruff, Verbruggen, Shaklai or any combination thereof.

Additionally, the Applicants presented compelling evidence directed to long-felt need and commercial success in the Amendment and Response to Office Action filed on June 16, 2004 that further supports the non-obviousness of the present invention.

Therefore, independent claims 1, 22 and 161 are not obvious in view of Carr, Woodruff, Breen, Verbruggen, Shaklai or any combination thereof and, thus, should be in a condition for allowance.

V. Dependent Claims 2-21, 23-37, 87-90 and 162-171

Dependent claims 2-21, 23-37, 87-90 and 162-171, which depend directly or indirectly on independent claim 1, 22 or 161, are not obvious in view of Carr, Woodruff, Breen, Verbruggen, Shaklai or any combination thereof for at least the same reasons discussed with respect to claims 1, 22 and 161. Thus, claims 2-21, 23-37, 87-90 and 162-171 should be in a condition for allowance.

VI. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkens & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01080USPT.

Respectfully submitted,

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